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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ALEXANDER, LYLE	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/697,351	BUECHLER, KENNETH F.	
	Examiner	Art Unit	
	Lyle A. Alexander	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,3-6 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The 7/2/09 amendments add the language "a lidless device." It is not clear what structure is intended by "lidless." Lidless is discussed on page 32 line 6 of the original specification "... immunoassay devices, such as, to dipsticks or lidless devices ...". If Applicant's what a "dip stick" structure, then they should claim the structure. The presently claimed structure could be read on any device that does not have a cover, but is not descriptive of what structure is actually intended.

Additionally, claims 6 and 8 specify there is a "second surface spaced ... from said nonporous surface" which is confusing because the "second surface" could be considered a "lid." These limitations do not further limit independent claim 1 that prohibits the presence of a "lid" (e.g. "lidless").

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1and 3-6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Findlay et al. (USP 5,514,550).

Findlay et al. teach an assay device having a nonporous surface (see col. 14 lines 9+) with particles immobilized to the surface. Column 6 lines 31-41 teach the particles are in the range of 0.1-10 microns and preferably between 0.1 and 5 microns (also see claim 3). The claimed protrusions extending between 1 microns to 0.5mm has been read on the taught immobilized particles. Column 6 lines 41-55 teach the claimed materials of the particles. Example 2 in column 13 expressly teaches the particles are made of polystyrene. The surface of Findlay et al. would have been expected to have at least one depression/protrusion between 1nm and 0.5mm as a manufacturing imperfection. The Office has read this on claim 3 "... a textured surface comprising one or more depressions and/or protrusion extending between 1nm and 0.5mm... ". Column 5 lines 43-52 teach the probe is sandwiched between two opposing sheets and have been read on the claimed "second surface" of claim 6. Additionally, it would have been inherent the two sheets sandwiching the probe would be a capillary distance apart because if the sheets were not a capillary distance apart, the fluid would not flow and contact the probes making the device inoperable.

Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Wu.

Wu teaches a nucleic acid amplification kit. Column 10 lines 47-64 teach the surface can be nonporous. Column 9 lines 3-9 teach the particles immobilized on the surface could be from 0.01-10 microns. Column 9 lines 38-50 teach the particles can

be made of polystyrene. The claimed protrusions extending between 1 microns to 0.5mm has been read on the taught immobilized particles. The surface of Wu et al. would have been expected to have at least one depression/protrusion between 1nm and 0.5mm as a manufacturing imperfection. The Office has read this on claim 3 "... a textured surface comprising one or more depressions and/or protrusion extending between 1nm and 0.5mm... ".

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. in view of Oosta et al.(USP 5,478,751).

See Wu et al. supra.

This reference is silent to placing a second surface at a capillary distance from the nonporous surface and specifically a distance of 0.01mm to 0. 2mm.

Oosta et al. teach an immunodiagnostic device that binds target ligands. In column 7 lines 20-38, Oosta et al. teaches a cover on the device to protect the binding reagents. Additionally, column 6 lines 37-55 teach the device is a capillary flow device and all of the dimensions are such to promote capillary flow. In light of the teachings of column 6, the Office has read Oosta et al. as teaching the cover taught in column 7 is spaced "... at a capillary forming distance ..." as presently claimed.

It would have been within the skill of the art to modify Findlay et al. or Wu et al. and provide a second surface, at a capillary forming distance, to protect the binding reagents.

The spacing of the first and second surfaces, would have been a result effective variable yielding the well known and expected result of capillary flow (See *In re Boesch (205 USPQ 215)*. It would have been within the skill of the art as optimization of a result effective variable to further modify Wu et al. in view of Oosta et al. and space the two layers at a distance between 0.01mm to 0. 2mm to achieve the well known and expected results of capillary flow.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Findlay et al.

See Findlay et al. supra.

Findlay et al. are silent to placing a second surface at a distance of 0.01mm to 0. 2mm.

The spacing of the first and second surfaces, would have been a result effective variable yielding the well known and expected result of capillary flow (See *In re Boesch (205 USPQ 215)*. It would have been within the skill of the art as optimization of a result effective variable to modify Findlay et al. and space the two layers at a distance between 0.01mm to 0. 2mm to achieve the well known and expected results of capillary flow.

Response to Arguments

Applicant's arguments filed 7/2/09 have been fully considered but they are not persuasive.

The 7/2/09 terminal disclaimers have obviated all of the double patenting rejections.

The 7/2/09 amendments that cancelled claim 7 have obviated the 35 USC 112 1st and second paragraph issues over this claim.

Applicant state the priority for the claimed "nonporous surface" can be traced back to parent patent USP 5,458,852 column 2 lines 4-7. The Office agrees this portion of the specification appears to teach nonporous surfaces. However, upon further consideration of USP 5,458,852, this patent does not appear to support the presently claimed particle range of "1 nm to 5 microns." The patent teaches in column 8 line 13 the particles have a range of "0.01 microns to 10 microns" which has been read as 10 nm to 10 microns which does not support the claimed range from 1 nm to 9.99... nm. For this reason, the Office maintains the effective filing date of the instant application is 7/11/00. However, in the event Applicant amends the claims to be supported by USP 5,458,852, the Office would maintains the rejections of record under 35 USC 102(a and/or e).

Applicant states the cited prior art does not teach the claimed "antibodies or fragments thereof bind specifically to one or more target ligands ...". Findlay et al. clearly teach in column 5 lines 1-19 and in column 7 line 24 antibodies bound to the particles which is indistinguishable from the instant claims. Wu et al. teach in their abstract the capture probe is complementary to the target nucleic acids which is also indistinguishable from the instant claims.

Conclusion

This is a RCE of applicant's earlier Application No. 10/697,351. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/
Primary Examiner, Art Unit 1797